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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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CYTYC CORPORATION			GRUN, JAMES LESLIE	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/774,144	HICKOK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	JAMES L. GRUN	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 21 March 2008 and 20 June 2008.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 67-94 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 67-94 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 20 June 2008 has been entered. Claims 67-94 are newly added. Claims 1-66 have been cancelled.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 67-76, 79, and 81-94 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record in the prior rejection of the similar subject matter of claims 35-44, 47, and 49-64 as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, particularly the invention commensurate in scope with these claims.

As set forth the prior art would suggest that an ability to prolong a pregnancy at risk for preterm delivery is not a property known or common to the laundry list of progestational agents

disclosed by applicant (see e.g. Goldstein et al. or Keirse in this regard). “[T]here are large differences among the many agents considered to be progestational on the basis of pharmacological tests” (Keirse, page 149), including differences in teratogenic, metabolic, or hemodynamic effects of natural progesterone compared to artificial progestagens (da Fonseca et al., page 419). Many agents are considered to be progestational on the basis of pharmacological tests, yet the results of the use of progesterone-related agents generally for prolonging a pregnancy at risk for preterm delivery, the only reason for its use in the instant specification (see e.g. pages 1-3 or 6), would seem unknown and unpredictable because only specific agents were tested and suggested to have that ability (see e.g. Goldstein et al. or Keirse or da Fonseca et al. or Meis et al.). The specification merely suggests the use of agents that retain the activity of progesterone to inhibit or delay delivery, but provides no guidance for which agents retain such activity. Applicant has provided nothing on the record to predictably link the use of a progesterone-related agent, such as those listed in the specification, as a contraceptive (i.e., **preventing** a pregnancy, as in Spicer et al. or Peters et al.) to its successful use as an agent for **prolonging** a pregnancy at risk for preterm delivery. It is also noted that applicant’s specification provides no working examples of pregnancy prolongation other than that demonstrated in the art with progesterone (da Fonseca et al.) or 17 $\alpha$ -hydroxyprogesterone (Johnson et al., Yemini et al., Keirse, or Meis et al.) or omega-3 fatty acid supplementation (Allen et al. or Olsen et al.). As set forth, random experimentation unguided by applicant to determine agents that do or do not function in the invention suggested by applicant’s specification is undue experimentation. Absent further guidance from applicant, and such

random unguided undue experimentation, one would not be assured of the ability to practice the invention commensurate in scope with these claims.

Applicant's arguments filed 20 June 2008 have been fully considered but they are not deemed to be persuasive.

Claims 67-94 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regard to these claims, the specification, as originally filed, does not provide support for the patient population as is now claimed. Although the methods can be used with any pregnant patient, applicant teaches monitoring the level of markers particularly in patients with risk factors for preterm delivery. Applicant does not define, and one would not readily know absent further guidance from applicant, what patients are encompassed by the current criteria of "asymptomatic." Although one of skill in the art might realize from reading the disclosure that any pregnant patient is useable in the invention, such possibility of use does not provide explicit or implicit indication to one of skill in the art that only "asymptomatic" patients were originally contemplated as part of applicant's invention and such possibility of use does not satisfy the written description requirements of 35 U.S.C. § 112, first paragraph. Note that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement. Applicant is requested to direct the Examiner's attention to specific

passages where support for these newly recited limitations can be found in the specification as filed or is required to delete the new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 67-94 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 67-94, “the” level lacks antecedent basis.

In claim 68, “the” locations lack antecedent basis. In this claim, improper Markush language is used to claim the members of the group. The alternatives “or” or “selected from the group consisting of...and” are acceptable.

In claim 71, “the” start lacks antecedent basis.

In claim 75, “the” onset lacks antecedent basis.

In claim 80, “.alpha.” is not clear.

In claim 81, “the” therapeutically effective amount lacks antecedent basis.

In claim 83, it is not clear if “the” sample is the same sample tested in claim 67 or a newly obtained sample.

In claims 85 or 86, “the” locations lack antecedent basis.

In claim 87 and claims dependent thereupon, the interrelationships of the steps are not clear because it is not clear if the contacted sample of step a) is that contacted in step b).

In claim 91 and claims dependent thereupon, it is not clear how detection of a complex with anti-fibronectin antibody specifically detects fetal fibronectin.

In claim 92, the interrelationships of the steps are not clear because it is not clear if the contacted sample of step a) is that contacted in step c).

Applicant's arguments filed 20 June 2008 have been fully considered but they are not deemed to be persuasive.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
- (c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 67-76 and 79-94 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Leavitt et al. (WO 94/17405) in view of any of Johnson et al. (NEJM 293: 675, 1975), Meis et al. (Am. J. Obstet. Gynecol. 187: S54, 2002), or Keirse (Br. J. Obstet. Gynaecol. 97: 149, 1990), and further in view of Weiner et al. or Andersen et al. for reasons of record in the prior rejection of the similar subject matter of these claims as found in claims 35-44 and 47-64.

The invention as instantly disclosed, with regard to determinations of fetal fibronectin or total fibronectin as biochemical markers of impending imminent preterm delivery and of insulin-like growth factor binding protein-1 to determine fetal membrane status to aid clinical decisions regarding administration of treatments to prolong pregnancy in pregnant patients at 12 to 37 weeks gestation (see e.g. pages 4-6, 8), is essentially as disclosed and claimed in the reference of Leavitt et al. except for the instant alternative use of estriol determination as a biochemical marker of impending preterm labor. In contrast to the invention as instantly disclosed and claimed, Leavitt et al. does not teach the specific use of progestational agents as the agents to prolong the pregnancy determined to be at risk for preterm delivery in the absence of ruptured membranes.

Any of Johnson et al. (NEJM 293: 675, 1975), Meis et al. (Am. J. Obstet. Gynecol. 187: S54, 2002), or Keirse (Br. J. Obstet. Gynaecol. 97: 149, 1990) teach the efficacy of progesterone treatments in reducing preterm delivery.

Weiner et al. or Andersen et al. teach that treatment with tocolytic agents is not beneficial (Weiner et al.) and not recommended (Andersen et al., page 346; Weiner et al.) in patients with rupture of membranes. Progestational agents are known as among the tocolytic agents that function to **prevent** or reduce contractions prior to preterm labor (see e.g. Andersen et al. (page 345)).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have tested a pregnant patient determined to have biochemical markers indicative of impending preterm delivery for the status of the fetal membranes and to treat those patients with intact fetal membranes indicated as at risk of having impending delivery with a

pregnancy-prolonging agent because of the direct suggestion in Leavitt et al. to do so. One of ordinary skill would have had ample motivation to determine and/or confirm fetal membrane rupture in patients with impending delivery, as determined by any method, because determination of ruptured fetal membranes is of unquestioned importance relating to the health of both the mother and the fetus and for the clinical management of pregnant patients, particularly in those patients at risk for preterm birth wherein a decision regarding the use of tocolytic/pregnancy-prolonging agents must be weighed (Leavitt et al., Weiner et al., or Andersen et al.). One would have been motivated to treat a patient so identified with a known efficacious pregnancy-prolonging agent, such as progesterone as taught by any of Johnson et al., Meis et al., or Keirse, in view of the direct suggestion to do so in Leavitt et al. and because one would have had an extremely reasonable expectation that a known efficacious pregnancy-prolonging agent would successfully perform its desired function in the method. It would have been obvious to formulate the reagents required to perform the method of Leavitt et al., as modified, into a kit since that is conventional for convenience, reproducibility, and economy.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Claims 77 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leavitt et al., in view of any of Johnson et al., Meis et al., or Keirse, and further in view of Weiner et al. or Andersen et al., as applied to claims 67-76 and 79-94 above, and further in view of Allen et al. (Exp. Biol. Med. 226: 498, 2001) or Olsen et al. (Lancet 339: 1003, 1992).

The teachings of Leavitt et al., Johnson et al., Meis et al., Keirse, Weiner et al., and Andersen et al. are as set forth above and differ from the invention as instantly claimed in not teaching omega-3 fatty acids as a pregnancy-prolonging agent.

Either of Allen et al. or Olsen et al. teach the efficacy of omega-3 fatty acid supplementation treatments in reducing preterm delivery.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have supplemented the diet of those patients with intact fetal membranes indicated as at risk of having impending delivery with a pregnancy-prolonging agent because of the direct suggestion in Leavitt et al., as modified, to do so. One would have been motivated to treat a patient so identified with a known efficacious pregnancy-prolonging agent, such as omega-3 fatty acids as taught by either of Allen et al. or Olsen et al., in view of the direct suggestion to do so in Leavitt et al., as modified, and because one would have had an extremely reasonable expectation that a known efficacious pregnancy-prolonging agent would successfully perform its desired function of prolonging pregnancy in the method. It would have been further obvious to have administered a plurality of pregnancy-prolonging agents to the identified patients for the combined benefits of each agent.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Applicant's arguments filed 20 June 2008 have been fully considered but they are not deemed to be persuasive.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Dullien (US 5,480,776) teaches determinations of unconjugated estriol as indicative of impending preterm labor essentially as instantly disclosed.

Dullien (US 5,370,135) teaches determinations of unconjugated estriol as indicative of impending preterm labor essentially as instantly disclosed and teaches the determinations for monitoring the start and/or continuation of tocolytic therapy. However, progesterones are not specifically mentioned as a tocolytic/ pregnancy-prolonging agent.

Any of Yemini et al. (Am. J. Obstet. Gynecol. 151: 574, 1985) or Noblot et al. (Eur. J. Obstet. Gynecol. Rep. Biol. 40: 203, 1991) also teach the efficacy of progesterone treatments in reducing preterm delivery.

Terao et al. (US 5,650,394) teach determinations of fetal fibronectin as indicative of impending preterm labor essentially as instantly disclosed and teach the determinations for monitoring the start and/or continuation of tocolytic, urinastatin, and antibiotic therapy. However, progesterones are not specifically mentioned as a tocolytic/ pregnancy-prolonging agent.

Lockwood et al. determined the level of fetal fibronectin in vaginal and/or cervical samples obtained from the cervical os and posterior fornix of control pregnant patients, patients with preterm rupture of fetal membranes, and patients with intact membranes having preterm contractions. Samples from the control population were obtained a plurality of times, average of four, between 5 and 40 weeks of gestation (page 670, bottom of column 1 and Figure 1). Between weeks 21 and 37 of gestation (i.e. preterm), elevated levels of cervicovaginal fetal fibronectin were correlated with

either: preterm rupture of fetal membranes and impending delivery in patients; or, impending preterm delivery in patients with intact membranes (page 669, Abstract, and page 671, column 2). Lockwood et al. also determined fetal lung maturity in amniotic fluid samples obtained from control patients also monitored for cervicovaginal fetal fibronectin (page 670, bottom of column 1). The reference teaches that the detection of fetal fibronectin in patients with impending preterm delivery having intact membranes may be the result of release of fetal fibronectin from the chorion or from the extracellular matrix of the chorion-decidua membrane junction (Abstract, or pages 673-674). However, the reference does not teach the combined detection of fetal fibronectin and insulin-like growth factor binding protein 1 (IGFBP-1) in samples from the same patient, or kits with both anti-fetal fibronectin and anti-insulin-like growth factor binding protein 1 antibodies.

Senyei et al. (U.S. Patent No. 5,468,619; hereafter '619) teach the detection of total fibronectin in samples obtained from the cervical os and/or posterior fornix as indicative of impending delivery. However, the reference does not teach the combined detection of total fibronectin and insulin-like growth factor binding protein 1 (IGFBP-1) in samples from the same patient, or kits with both anti-fibronectin and anti-insulin-like growth factor binding protein 1 antibodies.

Kanayama et al. determined elastase as a marker of imminent delivery and the level thereof as a further indicator of impending premature rupture of membranes. However, the reference does not teach the combined detection of elastase and insulin-like growth factor binding protein 1 (IGFBP-1) in samples from the same patient, or kits with both anti-elastase and anti-insulin-like growth factor binding protein 1 antibodies.

Rutanen et al. (American Journal of Obstetrics and Gynecology 164(1): 258, Abstract no. 38, 1991) obtained cervical secretion samples from patients and determined, with sandwich immunoassays using two monoclonal anti-insulin-like growth factor binding protein 1 antibodies, the level of insulin-like growth factor binding protein 1 (IGFBP-1) in the samples for the purpose of diagnosing premature fetal membrane rupture. Rutanen et al. detected levels of IGFBP-1 in samples of cervical secretions in three ranges: undetectable in nonpregnant patients; a range of from undetectable to 90 ng/ml (i.e. 90 µg/l) in pregnant patients with intact fetal membranes with or without labor; and an increased level ranging from 175 to 20,000 ng/ml (i.e. µg/l) in pregnant patients with or without labor susceptible to delivery due to rupture of membranes. The reference also teaches levels of IGFBP-1 detectable in amniotic fluid, maternal serum, maternal urine, and seminal plasma.

Rutanen (WO 92/12426; hereafter '426) discloses a method and kit for the determination of fetal membrane rupture by determination of amniotic fluid presence in the vagina (e.g.: claims; ¶ bridging pages 3-4). In the method, a vaginal secretion sample is obtained from a patient and the level of insulin-like growth factor binding protein 1 (IGFBP-1) in the sample is determined by immunoassay, preferably using two monoclonal anti-insulin-like growth factor binding protein 1 antibodies. The test can be so designed that sources of IGFBP-1 other than amniotic fluid, such as blood, cannot cause false positive results in the test conditions used (pages 10-15; ¶ bridging pages 3-4). Rutanen ('426) also teaches the importance of diagnosis of premature fetal membrane rupture (page 1) with regard to increased risk of infection and increased mortality.

Rutanen et al. (Clinica Chimica Acta 214(1): 73, 1993), with sandwich immunoassays using two monoclonal anti-IGFBP-1 antibodies, selected from 6303 and 6305 (e.g. page 75), one

of which was labelled, provided in a kit, detected levels of IGFBP-1 in samples of cervical secretions, extracted into 0.5 ml of diluent, in various ranges (e.g. pages 76-78): undetectable (i.e. < 0.5 µg/l) to < 1 µg/l in nonpregnant patients; a range of from undetectable (i.e. < 0.5 µg/l) to detectable (i.e. ≥ 0.5 µg/l) up to 90 µg/l (median 8.6 µg/l) in pregnant patients with apparently intact fetal membranes and not in labor (i.e. of normal or low susceptibility to delivery soon); and, an increased level greater than 100 µg/l ranging from 175 to 20,000 µg/l in pregnant patients highly susceptible to delivery due to rupture of fetal membranes. The reference teaches the decidual cell production of IGFBP-1 (e.g. Fig. 3, and page 80) and the chorionic membrane production of fetal fibronectin. The reference suggests that, as does fetal fibronectin, IGFBP-1 may leak into the vagina when the cervix dilates and the chorion is detaching from the decidua in the lower uterine segment (page 80).

Rutanen et al (Clinica Chimica Acta 253: 91, 1996) teach a dipstick sandwich immunoassay using monoclonal anti-IGFBP-1 antibodies 6303 and 6305 for detection of ruptured fetal membranes.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. L. G./  
James L. Grun, Ph.D.  
Examiner, Art Unit 1641  
July 29, 2008

/Long V Le/  
Supervisory Patent Examiner, Art Unit 1641